

Application No. 10/069,455

REMARKS

In the application filed on July 08, 2002, original claims 1 - 40 are pending and under consideration. Original claims 1 - 5 are compound claims. Original claims 6 - 13 are composition claims. Original claims 14 - 40 are use claims.

Prior to providing details of the Applicant's present Amendment in response to the Office Action dated Mar. 03, 2004, the Applicant respectfully makes the Examiner aware of the USPTO Office Communication (PTO-90C), dated July 08, 2004, a copy of which is provided along with the present Amendment, wherein the Legal Instruments Examiner (LIE), Norma Villarivera, indicated that "The amendment document filed on 3-3-04 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003". More specifically, the LIE indicated non-compliance of the document regarding category 4. - Amendments to the claims, sub-category C. - Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.

By this Response, the Applicant respectfully informs the Examiner that the Applicant did not file anything relating to prosecution of the present application on Mar. 03, 2004, and therefore, the above described USPTO Office Communication was mistakenly sent to the Applicant, and the content thereof is irrelevant. The Applicant respectfully requests acknowledgement of such by the Examiner.

Reconsideration of the above identified application in view of this Amendment is respectfully requested. This Amendment is in response to the Office Action dated Mar. 03, 2004. By said Office Action, the Examiner requested another copy of the signed

declaration. Claims 1, 6, 14, 16, 21 - 23, and 30 - 34, were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 was stated as containing a limitation lacking antecedent basis. Claims 6 - 40, were rejected under 35 U.S.C. 112, first paragraph, regarding lack of enablement. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Lin (Journal of Polymer Science, Polymer Chemistry Edition), as being anticipated by Gozlan et al. (Journal of Heterocyclic Chemistry), and as being anticipated by Schindler (US Pat. No. 2,976,281). Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Buckler et al. (US Pat. No. 4,495,281). Claims 23, 30, 32, 34, and 35, were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Ruger et al. (U.S. Pat. No. 5,264,432, cited by the Applicant). Claims 3 - 5 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 14, 15, 21, 23, 24, 30, 32, 34, and 35, were allowable over Kawashima (US Pat. No. 3,842,640).

By this Amendment, the Applicant has amended claims 1, 3, 4, 6, 14, 23, 27, 32, 33, 34, and 38. Claims 2, 11, and 18, have been cancelled. Claims 5, 7 - 10, 12 - 13, 15 - 17, 19 - 22, 24 - 26, 28 - 31, 35 - 37, and 39 - 40, remain as originally filed. New claims 41 - 46 have been added.

Briefly, the present invention relates to tricyclic compounds of the 11-oxo-dibenzodiazepin and dibenzoazepin families, and their new therapeutic uses as defibrillating, and/or anti-fibrillatory, and/or anti-arrhythmic and/or anti-ischemic drugs. More particularly, the present invention relates to 5(N-acyl)-derivatives and 5(N- β -aminoalcohol)-derivatives of 11-Oxo-10,11-dihydro-dibenzo[b,e] [1,4]diazepin and

10,11-dihydro-dibenzo[b,f]azepin, compositions including same, methods of their synthesis, purification and formulation and their use in prevention and treatment of cardiac disorders, such as, but not limited to, arrhythmia and ventricular fibrillation.

Oath/Declaration

In Examiner's detailed action item 2, the Examiner stated that he did not see the actual Oath/Declaration form in the electronic file. The Examiner requested another copy of the signed declaration to be added to the file. Such is separately included as part of this Response.

35 U.S.C. 112, Second Paragraph Claims Rejections

By Examiner's detailed action item 3, claims 1, 6, 14, 16, 21 - 23, and 30 - 34, were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner rejected inclusion of the term "diamino" as a possible R1 substituent in said claims.

By this Amendment, the Applicant has cancelled the term "diamino" as a possible R1 substituent in original independent claims 1, 6, 14, 23, 32, and 34, and therefore, in original claims 16, 21, 22, 30, 31, and 33, depending therefrom, as evidenced by absence of the term "diamino" in currently amended claims 1, 6, 14, 23, 32, and 34.

Thus, this 35 U.S.C. 112, second paragraph rejection by the Examiner is completely overcome.

By Examiner's detailed action item 4, claims 6, 14, 23, 32, and 34, were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner rejected recitation of the phrase "wherein n is an integer" in said claims. The Examiner further inquired as to whether there is any size limit upon n, is it restricted to 0 - 5, or could it be infinitely large?

By this Amendment, the Applicant has amended recitation of the phrase "wherein n is an integer" in original claims 6, 14, 23, 32, and 34, to read "wherein n is an integer being 0 - 5", as appearing in currently amended claims 6, 14, 23, 32, and 34.

Support for this amendment is clearly and literally found throughout the originally filed specification. Specifically, in the Summary section, on page 4; in the Description section, on pages 7, 9, and 10, wherein it is stated for each recited substituent, $C(=O)(CH_2)_nNR'R''$ and $(CH_2)_nCHOHCH_2NR'R''$, including "n" in its formula, that "... n is an integer" and that "... n being 0-5". Additional support for this amendment is found in the Examples 1 - 7, wherein any appearance of, and/or reference to, either of these substituents clearly indicates that "n is an integer being 0 - 5".

Thus, this 35 U.S.C. 112, second paragraph rejection by the Examiner is completely overcome.

By Examiner's detailed action item 5, claim 18 was stated as containing a limitation lacking antecedent basis. Specifically, the Examiner stated that in line 1 of claim 18, recitation of the limitation "wherein A is *** or C=O" lacks antecedent basis in the parent claim 14. The Applicant respectfully points out to the Examiner that the same lack of antecedent basis exists in claim 11, depending from 'parent' claim 6.

By this Amendment, the Applicant has cancelled claims 11 and 18.

Thus, this lack of antecedent basis rejection by the Examiner is completely overcome.

35 U.S.C. 102(b) Rejections

By Examiner's detailed action item 7, claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Lin (Journal of Polymer Science, Polymer Chemistry Edition). Specifically, the Examiner stated that the compound shown in Examiner's detailed action item 7 fits formula (II) with $R_Q = R_T = \text{hydrogen}$, $q = t = 1$, and $R_1 = \text{the unsaturated alkyl group vinyl}$, and has Registry Number 73046-29-4.

By this Amendment, the Applicant has amended independent claim 1 by having cancelled "unsaturated alkyl" as being a possible R_1 substituent, as evidenced by its absence in amended claim 1.

Thus, this 35 U.S.C. 102(b) rejection by the Examiner is completely overcome.

By Examiner's detailed action item 8, claim 1 was rejected under 35 U.S.C. 102(b), as being anticipated by Gozlan et al. (Journal of Heterocyclic Chemistry). Specifically, the Examiner stated that the compound shown in Examiner's detailed action item 8 fits formula (II) with $R_Q = R_T = \text{hydrogen}$, $q = t = 1$, and $R_1 = \text{the unsaturated alkyl group allyl}$, and has Registry Number 74074-21-8.

Based on immediately preceding Applicant's amendment of independent claim 1 by having cancelled the "unsaturated alkyl" as being a possible R_1 substituent, as evidenced by its absence in amended claim 1, this 35 U.S.C. 102(b) rejection by the Examiner is completely overcome.

By Examiner's detailed action item 9, claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Buckler et al. (US Pat. No. 4,495,281). Specifically, the Examiner stated that the compound shown in Examiner's detailed action item 9 fits formula

By Examiner's detailed action item 11, claims 23, 30, 32, 34, and 35, were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over, Ruger et al. (U.S. Pat. No. 5,264,432, cited by the Applicant). Specifically, the Examiner stated that the compound shown in Examiner's detailed action item 11 fits the formula of claim 14 (Applicant believes that the Examiner actually meant to have indicated the formula of each claim 23, 32, and 34) with $A = C=O$, $B = NH$, $R_Q = R_T = \text{hydrogen}$, $q = t = 1$, and $R1 = C(=O)(CH_2)_nNR'R''$, with $n = 3$, and $R' = R'' = \text{ethyl}$, and has Registry Number 134000-64-9.

By this Amendment, the Applicant has amended each independent claim 23, 32, and 34, by having cancelled " $C=O$ " as being a possible A substituent, as evidenced by its absence in each amended claim 23, 32, and 34.

Thus, this 35 U.S.C. 102(b), or alternatively, 35 U.S.C. 103(a) rejection by the Examiner is completely overcome.

Since each original claim 27 and 38, depending from original independent claims 23 and 32, respectively, includes recitation wherein the A substituent can be " $C=O$ ", by this Amendment, each claim 23 and 32 has also been amended by having cancelled " $C=O$ " as being a possible A substituent, as evidenced by its absence in each amended claim 23 and 32.

By this Amendment, in addition to the above described and fully supported amendments of independent claim 23, the Applicant has further amended independent claim 23 by amending the preamble to now read "A method for treating ventricular fibrillation in a subject, . . . ", as recited in amended claim 23. Support for this amendment is clearly found throughout the originally filed specification. Based on the content of the originally filed specification, and on the clarified, better defined, and further restricted,